REMARKS

Claims 1, 2, 4, 5 and 7-41 are pending in the application.

1. Rejection of Claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101

In the office action (page 2), the examiner rejected claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101 (statutory type double patenting rejection) as "claiming the same invention as that of claims 7 and 8 of prior U.S. Patent No. 6,586,628."

For the reasons set forth below, Applicants respectfully submit that a statutory type double patenting rejection of claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101 over claims 7 and 8 of U.S. Patent No. 6,586,628 ("the '628 patent") is improper under the patent laws. Thus, Applicants traverse this claim rejection, and request that it be withdrawn.

Law Concerning Double Patenting

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore. [35 U.S.C. §101.]

The double patenting doctrine precludes one person from obtaining more than one valid patent for the same invention, or for an obvious modification of the same invention. The primary purpose of the double patenting doctrine is to prevent an extension of the statutory period of monopoly that would occur if successive patents were allowed on the same basic concept. [Chisum on Patents, §9.01 and §9.03.]

Double patenting is concerned with attempts to *claim* the same or related subject matter twice. Thus, the standard of comparison for the second patent is what was *claimed* in the first patent, not what was disclosed in the specification of the first patent. It does not preclude a second patent on subject matter that is disclosed, but not claimed, in the first patent. [Chisum on Patents, §9.01 and §9.03; In re Bartfeld, 17 USPQ2d 1885 (Fed. Cir. 1991).] The disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even when the disclosure is found in the claims. Comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what

invention a claim *defines*, and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference. [MPEP §804; General Foods Corp. v. Studiengesellschaft Kohle mbH., 765 F. Supp. 121, 20 USPQ2d 1673 (S.D.N.Y. 1991), rev'd, 972 F. 2d 1272, 23 USPQ2d 1839 (Fed. Cir. 1992).]

There are generally two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. §101, which states in the singular that an inventor "may obtain a patent." The second is the "nonstatutory-type" double patenting rejection based upon a judicially created doctrine grounded in public policy that is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent. [MPEP §804.]

The double patenting determination involves two inquiries. First, is the same invention claimed twice? This inquiry hinges upon the scope of the claims in question. If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. §101 because an inventor is entitled to a single patent for an invention. If one claimed invention has a broader scope than the other, the court must proceed to a second inquiry: whether one claim defines merely an obvious variation of the other patent claim. Without a patentable distinction – because the pending claim defines merely an obvious variation of the patented claim – the patentee may overcome the double patenting rejection by filing a terminal disclaimer. [In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).]

The first question in a double patenting analysis is: Is the same invention being claimed twice? If the answer to that is no, a second questions must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. If the rejected claim defines more than an obvious variation, it is patentably distinct. [General Foods Corp. v. Studiengesellschaft Kohle mbH., *supra*, citing In re Vogel, 422 F.2d 438; 164 USPQ 619 (CCPA 1970).]

Where the claims of an application are substantively the same as those of a first patent, they are barred under 35 U.S.C. §101 – the statutory basis for a double patenting rejection. "Same invention" means identical subject matter. [MPEP §804; Miller v.

Eagle Mfg. Co., 151 U.S. 186 (Sup. Ct. 1984).] If there is any substantive difference, and not merely a difference in language, then the inventions are not the same no matter how small or how obvious those differences may be. [In re Plank, 339 F.2d 241, 158 USPQ 328 (CCPA 1968).] Claims that differ from each other (aside from minor differences in language, punctuation, etc.), whether or not the difference is obvious, are not considered to be drawn to the same invention for double patenting purposes under 35 U.S.C. §101. [MPEP §804.02.]

A test for "same invention" is whether one of the claims being compared could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention. [In re Vogel, *supra*.; General Foods Corp. v. Studiengesellschaft Kohle mbH., *supra*.] If there is an embodiment of the invention that falls within the scope of one claim, but not the other, identical subject matter is not defined by both claims, and statutory double patenting would not exist. If a second patent is not infringed by practice of the invention claimed in the first patent, the world will be free to use the invention of the first patent once it expires. [Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991).] Thus, there cannot be an unlawful extension of a monopoly. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to, or substantively the same as, a claim reciting the same compound except having a "chlorine" substituent in place of the "halogen" because "halogen" is broader than "chlorine." [MPEP §804.]

Two patents cannot be for the "same invention" in a double patenting sense when they claim different classes of subject matter, such as composition of matter v. process. [Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351 (Fed. Cir. 1986).]

A statutory type double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. [MPEP §804.]

Obviousness-type double patenting is a judge-made criterion adopted out of necessity where the courts were faced with a situation in which claims in two applications or patents were not drawn precisely to the same invention, but were drawn to inventions

so very much alike as to render one obvious in view of the other and to effectively extend the life of the patent that would have the earlier of the two issue dates. [Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990).]

The law of obvious-type double patenting requires only the determination of whether any claim in an application defines merely an obvious variation of an invention claimed in a prior issued patent, assuming common ownership and/or same inventive entity. [Ex parte Nesbit, 25 USPQ2d 1817 (Bd. Pat. App. & Int'f 1992).] The determining factor in deciding whether or not there is double patenting is the existence vel non of *patentable differences* between two sets of claims (whether such differences would have been obvious to one of ordinary skill in the art). [General Foods Corp. v. Studiengesellschaft Kohle mbH., *supra*, citing In re Borah, 354 F.2d 1009, 148 USPQ 213 (CCPA 1966).] The test for obvious modification is basically the same as the nonobviousness requirement of patentability, with the difference that the disclosure of the first patent may not be used as prior art. [Chisum on Patents, §9.03] Any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. §103 obviousness determination. [In re Bratt, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991).] The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (Sup. Ct. 1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. §103 are employed when making an obvious-type double patenting analysis. One claim is "patentably distinct" from another if the differences between them are such that the subject matter of one would not have been obvious over the subject matter of the other. [Davis v. Loesch, 998 F.2d 963, 27 USPQ2d 1440 (Fed. Cir. 1993).]

Difficulty arises in all obviousness-type double patenting cases of determining when a claim is or is not an obvious variation of another claim. A claim often does not describe any particular thing but instead defines the boundary of patent protection, and it is difficult to try to determine what is a mere obvious variation of a legal boundary. [In re Bratt, *supra*.]

Double patenting invalidity must be determined on a claim-by-claim basis. [Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 22 USPQ2d 1119 (Fed. Cir. 1992).]

Claims must be read as a whole in analyzing a claim of double patenting. [General Foods Corp. v. Studiengesellschaft Kohle mbH., *supra*.]

Domination and double patenting are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. [In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986); and In re Sarrett, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).]

In In re Sarrett, the CCPA stated the following with respect to genus and species claims (140 USPQ at 482):

> "The situation is that the oxidizing agent used in the process is claimed generically in the patent in the broadest possible terms as 'an oxidizing agent' and as specifically as possible in the application at bar by naming a single oxidizing agent - 'pyridine-chromium trioxide complex' – 'at a pH in excess of 7.0.' Clearly these two claims, to broad genus and narrow species, respectively, are patentably distinct." [Emphasis added.]

An inventor may make a new improvement on his own invention of a patentable character, so long as it is clearly distinct from, and independent of, one previously patented. [Miller v. Eagle Mfg. Co., *supra*.]

A disclaimer is a statement filed by an owner of a patent, or of a patent to be granted, in which the owner relinquishes certain legal rights to the patent. A terminal disclaimer under 37 C.F.R. §1.321(a) and (b) is used to disclaim, or dedicate a portion or the entire term of, all of the claims of a patent. By disclaiming that portion of the second patent which would extend beyond the expiration of the first, the patentee gives up any extension of patent protection that might have resulted. [MPEP §1490.] Any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted. [35 U.S.C. §253.] A terminal disclaimer ties the affected patents together; they expire on the same date and are enforceable only during periods in which they are owned by the same person. [35 U.S.C. §253.]

In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting. A terminal disclaimer cures the double patenting problem in all situations except when two patents are for identical subject matter. [37 C.F.R. §1.109.] A terminal disclaimer cannot be used to overcome a double patenting rejection when the claimed inventions are identical. [Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F. 2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991).]

The policy of the U.S. Patent and Trademark Office is to recognize terminal disclaimers, provided that they contain a provision requiring common ownership of the two patents. [Chisum on Patents, §9.04.] However, the statute does not provide for conditional disclaimers. Thus, a proposed disclaimer which is made contingent on the allowance of certain claims cannot be accepted. [MPEP §1490.]

It may be a close question whether a second application claiming subject matter related to the claims of an issued patent is an obvious variation, allowable only with a terminal disclaimer, or an unobvious variation, allowable without such a disclaimer. Faced with an initial double patenting rejection by an examiner, the applicant may wish to seek review with the Board of Appeals before entering a disclaimer. While conditional disclaimers are not allowed, the Board of Appeals has recognized at least two methods of achieving such review. [Chisum on Patents, §9.04.]

A terminal disclaimer, when filed to obviate a double patenting rejection in a patent application, or in a reexamination proceeding, must include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection. [37 C.F.R. §1.321(c).]

Law Concerning Obviousness

A patent may not be obtained though the invention is not identically disclosed or described as set forth in 35 U.S.C. §102 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in

the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. [35 U.S.C. §103.]

When analyzing the issue of obviousness, the differences between the prior art and the claims at issue must be ascertained. [Graham v. John Deer Co., 148 USPQ 459 (Sup. Ct. 1966)]. In connection with the first three "Graham factors," personnel of the U.S. Patent and Trademark Office should: (1) determine the "scope and content of the prior art;" (2) ascertain the "differences between the prior art and the claims at issue;" and (3) determine the "level of ordinary skill in the art." [Official Gazette, 1196 OG 38, March 11, 1997; ADT Corp. v. Lydall, Inc., 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998), citing In re Spada, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990) and Diversitech Corp. v. Century Steps, Inc., 850 F.2d. 1566, 7 USPQ2d 1315 (Fed. Cir. 1988).] With respect to the scope and content of the prior art, each reference must qualify as prior art under 35 U.S.C. §102, and should be in the field of the applicant's endeavor, or be reasonably pertinent to the particular problem with which the inventor was concerned. [*Id.*]

After the above analysis has been performed, the criterion for the determination of obviousness is whether the prior art would have suggested the invention to one of ordinary skill in the art, and that the invention would have a reasonable likelihood of success, viewed in light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, and not in Applicant's disclosure. [In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988)].

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. [In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).] Whether an art is predictable, or whether the proposed modification or combination of the prior art has a reasonable expectation of success, is determined at the time the invention was made. [Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).]

If the prior art does not teach any specific or significant utility for disclosed compounds, then the prior art is not sufficient to render structurally similar claims *prima facie* obvious because there is no motivation for one of ordinary skill in the art to make

the reference compounds, much less structurally related compounds. [MPEP §2144.09; In re Stemniski, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).]

The mere fact that the prior art can be modified does not make the modification obvious unless the prior art taught or suggested the desirability of the modification. [In re Gordon, 221 USPQ 1125 (Fed. Cir. 1984)]. The prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination. [Fromsom v. Advance Offset Plate, Inc., 225 USPQ 26 (Fed. Cir. 1985).] Good ideas may well appear 'obvious' after they have been disclosed despite having been previously unrecognized. [Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 43 USPQ2d 1294 (Fed. Cir. 1997)]. The Federal Circuit has held that "obvious to try" is not the standard to be employed under §103. [In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988).]

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. [MPEP §§2143 and 2143.03; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).]

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying of others, licensing and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of these secondary considerations is submitted, the examiner must evaluate the evidence. The weight to be accorded to the evidence depends on the individual factual circumstances of each case. [MPEP 2141; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987).] The ultimate determination on patentability is

made on the entire record. [In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).]

The patentability of a claim to a specific compound or subgenus embraced by a prior art genus should be analyzed no differently than any other claim for purposes of 35 U.S.C. §103. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. [MPEP §2144.08; In re Baird, 16 F.3d 380, 29 USPQ 2d 1550 (Fed. Cir. 1994).]

Homologs are compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups. Homologs which are far removed from adjacent homologs may not be expected to have similar properties. Homology and isomerism involve close structural similarity which must be considered with all other relevant facts in determining the issue of obviousness. [MPEP §2144.09; In re Mills, 281 F.2d 218, 126 USPQ 513 (CCPA 1960); In re Wiechert, 370 F.2d 927, 152 USPQ 247 (CCPA 1967).] Homology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed "as a whole." [MPEP §2144.09; In re Langer, 465 F.2d 896, 175 USPQ 169 (CCPA 1972).]

In In re Mills, *supra.*, a prior art disclosure of C_8-C_{12} alkyl sulfates was not sufficient to render *prima facie* obvious claimed C_1 alkyl sulfates.

A presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds (i.e. unpredictability in the pertinent art area). [MPEP §2144.09; In re May, 574 F.2d 1082, 197 USPQ 601 (1978).]

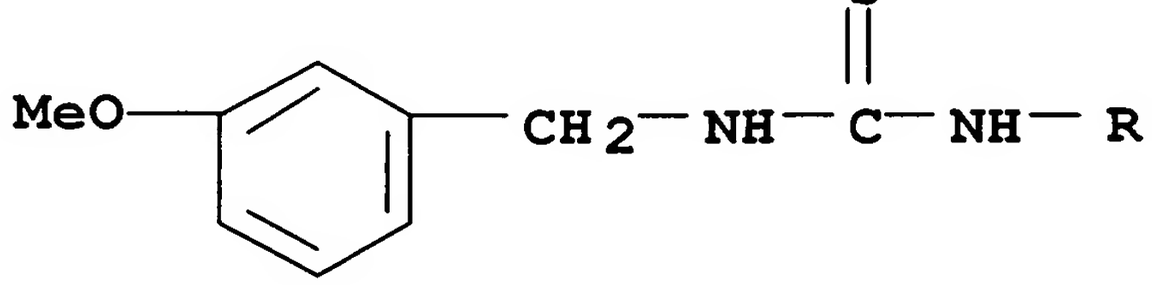
If the prior art does not teach any specific or significant utility for disclosed compounds, then the prior art is not sufficient to render structurally similar claims *prima facie* obvious because there is not motivation for one or ordinary skill in the art to make the reference compounds, much less any structurally related compounds. [MPEP §2144.09; In re Stemniski, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).]

If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. [In re Fine, *supra.*]

The Rejected Claims

Claims 1, 2, 5, 37 and 39 of the application, as they have been amended by the claim amendments set forth hereinabove, are set forth below. Claim 1 is an independent claim, and claims 2, 5, 37 and 39 are each dependent claims that ultimately depend upon claim 1.

1. A compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl, and wherein the compound enhances the oxidative stability of a lipid or oil to which the compound is added, with the proviso that R is not phenyl, octyl or octadecyl.

2. A compound of Claim 1 wherein R is a C_1 - C_{20} linear or branched alkyl.

5. A compound of Claim 2 wherein R is methyl, ethyl, propyl, isopropyl, butyl, isobutyl, tert-butyl, pentyl, 2-methyl pentyl, 3-methyl pentyl, hexyl, decyl, nonyl or dodecyl.

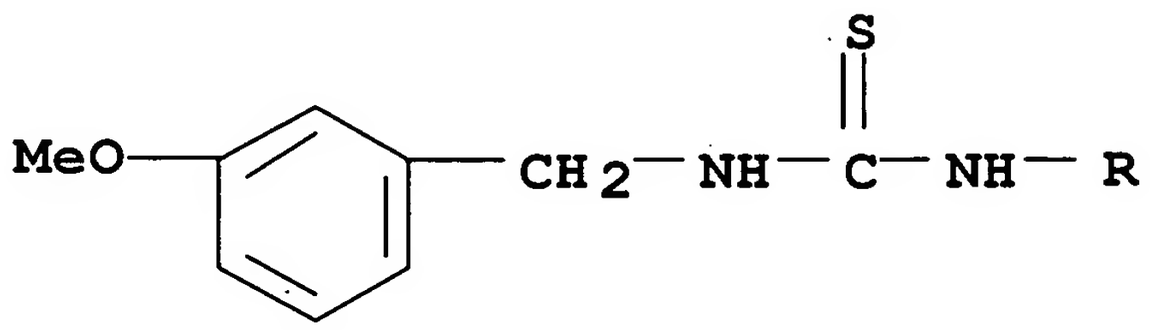
37. A compound of Claim 1 with the additional proviso that R is not methoxybenzyl or methyl.

39. A compound of Claim 5 wherein R is ethyl, propyl, isopropyl, butyl, isobutyl, tert-butyl, pentyl, 2-methyl pentyl, 3-methyl pentyl, hexyl, decyl, nonyl or dodecyl.

Claims 7 and 8 of U.S. Patent No. 6,586,628 B2

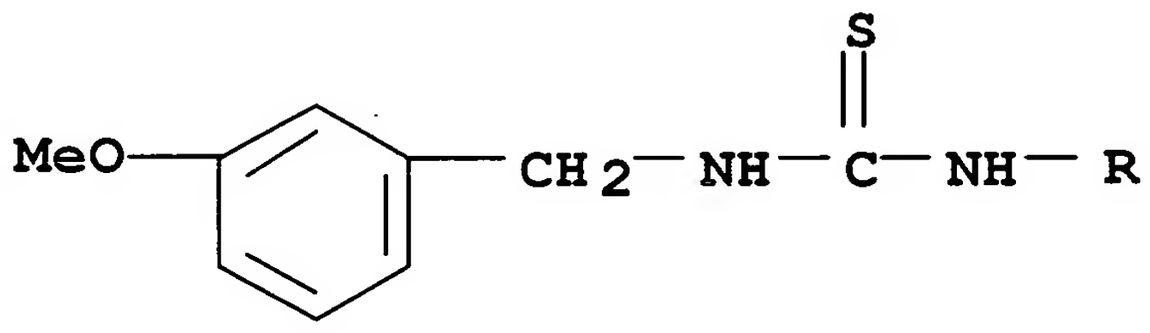
Claims 7 and 8 of U.S. Patent No. 6,586,628 B2 are set forth below.

7. A compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, and wherein the compound is 1-(3-methoxybenzyl)-3-octadecyl thiourea.

8. A compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, and wherein the compound is 1-(3-methoxybenzyl)-3-octyl thiourea.

Argument

"Statutory Type" Double Patenting

For the reasons set forth hereinbelow, Applicants respectfully submit that a "statutory type" double patenting rejection of claims 1, 2, 5, 37 and/or 39 of the application under 35 U.S.C. §101 over claims 7 and 8 of the '628 patent is improper under the patent laws, which are discussed in detail hereinabove.

A comparison of claims 1, 2, 5, 37 and 39 of the application with claims 7 and 8 of the '628 patent clearly shows that the "same" invention is not being claimed twice between any of the rejected claims and either claim 7 or claim 8 of the '628 patent (i.e., none of the rejected claims are identical in scope with either claim 7 or claim 8 of the

'628 patent, and each of claims 1, 2, 5, 37 and 39 of the application could be literally infringed without literally infringing either claim 7 or claim 8 of the '628 patent). Claims 7 and 8 of the '628 patent are clearly narrower than any of claims 1, 2, 5, 37 and 39 of the application. The examiner is referred to the discussion set forth hereinabove comparing a claim reciting a compound having a "halogen" substituent with a claim reciting the same compound having a "chlorine" substituent in place of the "halogen" substituent. The invention defined by the claim reciting a compound having a "halogen" substituent is not considered to be identical to, or substantively the same as, a claim reciting the same compound having a "chlorine" substituent in place of the "halogen" substituent (because "halogen" is broader than "chlorine").

In order to expedite the prosecution of the application, in the amendments set forth hereinabove, Applicants have amended claims 1, 5 and 39 of the application to further distinguish these claims from claims 7 and 8 of the '628 patent. Claim 1 has been amended to add the phrase "octyl or octadecyl" to the phrase "with the proviso that R is not phenyl," so that this proviso now reads, "with the proviso that R is not phenyl, octyl or octadecyl." This amendment has an effect of excluding octyl and octadecyl from the definition of the R variable in claim 1. Further, claim 5 and claim 39 were each amended to delete the word "octyl" from these claims. Because the amendment that was made to independent claim 1 is incorporated by reference into claim 2 and claim 37, both of which depend upon claim 1, claim 2 and claim 37 were not amended.

Applicants submit that the addition of the phrase "octyl or octadecyl" to the proviso that is present in claim 1 does not constitute new matter because such an addition has the effect of narrowing, not broadening, the invention that is claimed in this claim (excluding compounds that were encompassed within Applicants' originally-filed claims). The examiner is referred to In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977) and In re Driscoll, 195 USPQ 434 (CCPA 1977).

In In re Johnson and Farnham, provisos were added by the patent applicant to the originally-filed claims in order to exclude two species of chemical compounds that were originally encompassed within the originally-filed claims, and one of which was lost during an interference proceeding. In this case, like with amended claim 1 of the present application, the effect of the provisos was that the patent applicant was claiming less than

the full scope of his disclosure. The CCPA made the following statements in this case concerning the addition of provisos to claims:

> "Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable…
>
> To deny appellants the benefit of their grandparent application in this case would, as this court said in Saunders, let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed…
>
> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count…
>
> Here, as we hold on the facts of this case, the 'written description' in the 1963 specification supported the claims in the absence of the limitation, having described the whole necessarily described the part remaining." [Emphasis added.]

Like the facts in In re Johnson and Farnham, Applicants originally-filed specification contains a broad and complete generic disclosure, coupled with examples that are fully supportive of the invention claimed in amended claim 1, and Applicants have narrowed, rather than broadened, claim 1, with the full scope of the claimed invention being supported by the originally-filed specification, generically and by examples.

If the examiner takes the position that the amendment to claim 1 constitutes new matter, Applicants respectfully request that the examiner provide for Applicants the citations to the statutory, regulatory and/or case law that is used to support the examiner's position.

"Obviousness Type" Double Patenting

The examiner has not rejected claims 1, 2, 5, 37 and/or 39 over claims 7 and 8 of the '628 patent under the judicially created doctrine of "obviousness type" double patenting. Nevertheless, Applicants have also addressed this issue.

For the reasons set forth below, Applicants respectfully submit that a *prima facie* case of obviousness of the subject matter that is described in claims 1, 2, 5, 37 and 39 of the application, as amended in the amendments set forth hereinabove, over the subject matter that is described in claims 7 and 8 of the '628 patent, has not been established. Applicants submit that the subject matter that is described in claims 1, 2, 5, 37 and 39 of the application is patentably distinguished from the subject matter that is described in claims 7 and 8 of the '628 patent (i.e., that none of claims 1, 2, 5, 37 or 39 of the application defines merely an obvious variation of the subject matter that is described in claims 7 and/or 8 of the '628 patent).

First, Applicants respectfully submit that several structural, chemical and other differences exist between the subject matter that is described in claims 1, 2, 5, 37 and 39 of the application, as these claims have been amended hereinabove, and the subject matter that is described in claims 7 and 8 of the '628 patent, and that such differences are such that the subject matter described in claims 1, 2, 5, 37 and 39 of the application as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Further, for the reasons set forth hereinbelow, Applicants submit that the subject matter that is described in claims 7 and 8 of the '628 patent would not have suggested the invention that is described in claims 1, 2, 5, 37 and 39 of the application to one of ordinary skill in the art.

As a result of the amendments that have been made to claims 1, 5 and 39 of the application in the amendments set forth hereinabove, the compounds that are described in these claims are different structurally from the compounds that are described in claims 7 and 8 of the '628 patent. Claims 7 and 8 of the '628 patent describe 1-(3-methoxybenzyl)-3-octadecyl thiourea and 1-(3-methoxybenzyl)-3-octyl thiourea compounds, respectively. As a result of the amendment that has been made to independent claim 1 of the application in the amendments that are set forth hereinabove, claim 1 no longer includes compounds in which the R variable is defined as being either

octyl or octadecyl. Because dependent claims 2, 5, 37 and 39 of the application each ultimately depend upon claim 1, these claims each contain the same exclusions. Additionally, claim 5 and claim 39 of the application have each been amended to delete the word "octyl" from the claims.

Applicants respectfully submit that the differences that exist between the compounds that are described in claims 7 and 8 of the '628 patent and the rejected claims are patentable differences. As a result of the amendments that have been made to claims 1, 5 and 39 in the amendments presented hereinabove, and of such differences, the rejected claims do not even dominate claims 7 and/or 8 of the '628 patent (i.e., any domination has been eliminated). The Federal Circuit has said in In re Kaplan, *supra*, and in In re Sarrett, *supra*, that even domination, by itself, cannot support a double patenting rejection. The present factual situation is clearly less close of a situation than the factual situation described in In re Sarrett, wherein the two sets of claims were found to be patentably distinct.

Further, in In re Elpern, 140 USPQ 224 (CCPA 1964), the CCPA made the following statements about a fact situation in which the compounds described in the claims of a patent application were non-adjacent homologs of the compounds described in the prior art:

> "Where an invention for which a patent is sought is a compound which is a member of a homologous series and the prior art discloses a nonadjacent member of that series, we do not consider the Haas and Henz cases authority for the legal presumption of obvious of the claimed invention." [Emphasis added.]

With respect to the situation in which the claimed compounds differed from the prior art compounds only by an alkylene group, the Patent Office Board of Appeals stated in Ex parte Biel, 124 USPQ 109 (Bd. of App. 1958) that it considered this difference to be significant.

In Ex Parte Goonewardene and Love, 160 USPQ 287 (Bd. of App. 1968), alkylene-bridged claimed compounds were found to be free from prima facie obviousness over the unbridged compounds of the prior art.

In Ex parte Burtner and Arbit, 89 USPQ 547 (Bd. of App. 1950), the insertion of a $-CH_2CH_2-$ group between the -CO and -CO-COOH group of the prior art compounds was held to be a sufficient structural difference to render the claimed compounds patentable (in the absence of a showing of unexpected properties).

In a factual situation in which the only difference between the claimed compounds and the prior art compounds was a substitution of a sulfur atom of the claimed compounds for an oxygen atom of the prior art compounds, the Federal Circuit held in In re Grabiak, 226 USPQ 870 (Fed. Cir. 1985) that the U.S. Patent and Trademark Office did not establish a prima facie case of obviousness and, thus, did not shift to Grabiak the burden of coming forward with evidence of unexpected results. In this case, the Federal Circuit stated:

> "No reason exists for applying the law relating to structural obviousness of those compounds which are homologs or isomers of each other to this case. When the PTO seeks to rely upon a chemical theory in establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of that theory."

In In re Taborsky, 502 F.2d 775, 183 USPQ 50 (CCPA 1974), a 3-nitro-4′-fluorosalicylanilide, a compound that has two substituted benzene rings, one of which is substituted with fluorine, connected by a -CO-NH- group, was found to be free from prima facie obviousness over the corresponding 5-nitro-4′-chlorosalicylanilide. The CCPA noted that, to arrive at the fluoro-substituted compounds, the closest prior art compound, 5-nitro-4′-chlorosalicylanilide, had to be modified in two ways: (a) by changing the position of the nitro group on one of the benzene rings from the 5-position to the 3-position; and (b) by changing the identity of the halo-substituent on the 4-position of the other benzene ring from chloro to fluoro.

In In re Wagner and Folkers, 152 USPQ 552 (CCPA 1967), the CCPA reversed a decision of the Board of Appeals which affirmed an examiner's rejection of claims of a patent application which encompassed compounds which differed from the prior art compounds by the replacement of two different hydrogen atoms with methyl groups. The CCPA noted that the examiner had not explained how the prior art suggested the claimed compounds. The CCPA also stated the following concerning homology:

> "In the present case, we are not dealing solely with homology. The 'similarity' in this case is predicated on alkyl substitution in one or both of two specific places in the reference Compound B. There are, however, eleven places to make such substitutions, the prior art Compound B being one such possible combination of two substituents. Neither the examiner nor the Board pointed to facts demonstrating that it would have been obvious to one of ordinary skill in the art to make the substitution at those particular positions at which appellants have placed the substituents so as to enhance the biological or pharmaceutical activity of the compound instead of diminishing it, as in Compound C . . .
>
> Factually unsupported opinions of board members and examiners do not provide the factual basis required by the Supreme Court in the Deere case for the determination of obviousness under section 103. Neither can they establish a 'presumption' of obviousness. These subjective opinions are of little weight against contrary evidence. . .
>
> Neither the examiner nor the board has pointed to facts of record from which we can find that the prior art teachings suggest that the claimed compounds will possess enhanced antiviral activity . . .
>
> Our legal conclusion is that the facts of record do not supply a reasonable factual basis upon which to support the board's affirmance of the examiner's finding of obviousness of the claimed invention. The decision of the board is therefore reversed."

Additionally, independent claim 1 of the patent application (and claims 2, 5, 37 and 39, which depend upon claim 1) contains a proviso that, "wherein the compound enhances the oxidative stability of a lipid or oil to which the compound is added." In contrast, claims 7 and 8 of the '628 patent do not provide any teaching or suggestion regarding an enhancement of an oxidative stability of a lipid or oil. (As is discussed hereinabove, the disclosure of the '628 patent cannot be employed in support of a double patenting rejection.) Thus, claims 7 and 8 of the '628 patent do not teach or suggest all claim limitations, as is required to establish a *prima facie* case of obviousness.

Further, because claims 7 and 8 of the '628 patent do not disclose any specific or significant utility for the compounds described therein (without the use of the disclosure, which is prohibited), such claims are not sufficient to render the compounds described in claims 1, 2, 5, 37 and/or 39 *prima facie* obvious under In re Stemniski, *supra*, because there is not motivation for one of ordinary skill in the art to make the compounds

described in claims 7 and 8 of the '628 patent, much less any structurally similar or related compounds.

In view of the discussion above, it is clear that claims 7 and 8 of the '628 patent would not have suggested the invention that is described in claims 1, 2, 5, 37 and 39 of the present application to one of ordinary skill in the art.

Assuming arguendo that it would have been obvious to try to prepare the compounds that are described in claims 1, 2, 5, 37 and 39 of the application in view of claims 7 and 8 of the '628 patent, which Applicants submit that is was not, the Federal Circuit has held that "obvious to try" is not the standard under §103. [In re O'Farrell, *supra*.]

Second, for the reasons set forth below, Applicants respectfully submit that the subject matter that is described in claims 7 and 8 of the '628 patent would not have suggested that the invention that is described in claims 1, 2, 5, 37 and 39 of the application would have a reasonable likelihood of success.

There is no teaching, suggestion or other indication from claims 7 and/or 8 of the '628 patent (without the use of the disclosure, which is prohibited) that the compounds that are described in claims 1, 2, 5, 37 and 39 of the application would have an ability to successfully enhance the oxidative stability of a lipid or oil to which the compounds are added (a limitation that is present in each of these claims). Claims 7 and 8 of the '628 patent are completely silent regarding any activity or utility of the compounds described therein.

Further, for the reasons that are set forth below, Applicants submit that unpredictability exists in the art of disubstituted thiourea compounds.

Applicants have enclosed herewith a Second Declaration of Thomas P. Abbott under 37 C.F.R. §1.132 (a second declaration submitted for the application), which is incorporated herein by reference in its entirety. In this second Declaration, Dr. Abbott states that it is his opinion as an expert in the area of thiourea compounds that, for the reasons that he presents in the Declaration, a significant amount of unpredictability exists in the art of substituted thiourea compounds, to which claims 1, 2, 5, 37 and 39 are directed. He also discusses the fact that thiourea compounds that may appear to have similar chemical structures may have very different chemical properties.

In his second Declaration, Dr. Abbott states that the compounds that are described in claims 1, 2, 5, 37 and 39 of the application (as they have been amended in the amendments set forth hereinabove), are thiourea compounds that have a different molecular structure and chain length from the 1-(3-methoxybenzyl)-3-octadecyl thiourea and 1-(3-methoxybenzyl)-3-octyl thiourea compounds that are described in claims 7 and 8 of the '628 patent, respectively.

Dr. Abbott also states in the second Declaration that, as a polymer chemist, he is aware of a number of systems in which small differences in chain length of additives produce dramatic differences in compatibility with a polymer system, and provides examples of such systems. He further states that dispersibility and water, polymer and/or solvent solubility change dramatically and unpredictably with sidechain length for many different structures and applications, including disubstituted thioureas. Thus, he states that it is generally true that in polymer systems, or in lipids and/or oils, additives may have dramatically different effects with even small changes of one or two carbons in sidechain length, and that these effects are often surprising and unexpected. For example, he states that a disubstituted thiourea that has a low solubility in lipids and oils may have a significantly decreased ability to enhance the oxidative stability of a lipid or oil to which the compound is added. He states that the less soluble a substituted thiourea compound is in a lipid or oil to which the compound is added, the less the compound will have the ability to enhance the oxidative stability of the lipid or oil (because more of it remains in an undissolved state).

Moreover, in a Declaration of Thomas P. Abbott under 37 C.F.R. §1.132 dated July 3, 2003 (a first Declaration, which was submitted to the U.S. Patent and Trademark Office for the application on August 1, 2003), which is incorporated by reference herein in its entirety, Dr. Abbott also discusses the fact that thiourea compounds that may appear to have similar chemical structures may have very different chemical properties (i.e., that unpredictability exists in this area). For example, Dr. Abbott states (page 4) that it is his opinion as an expert in the area of thiourea compounds that, for the reasons that he presents in the declaration, 1,3-di(4-methoxybenzyl)thiourea has a different chemical structure, and different chemical properties, in comparison with 1,3-di(3-methoxybenzyl) thiourea. From experiments that are described in this Declaration, Dr. Abbott concludes

that the solubility of 1,3-di(4-methoxybenzyl) thiourea in refined meadowfoam seed oil is, at most, 25% (one fourth) of the solubility of 1,3-di(3-methoxybenzyl) thiourea in refined meadowfoam seed oil, and is probably less, and that 1,3-di(3-methoxybenzyl) thiourea is three times more effective as an agent to enhance the oxidative stability of a lipid or an oil to which it is added in comparison with 1,3-di(4-methoxybenzyl)thiourea. In this regard, he makes the following statements at the pages indicated:

Pages 6-7

"1,3-di(3-methoxybenzyl) thiourea differs from 1,3-di(4-methoxybenzyl)-thiourea both structurally, and in its chemical properties.

1,3-di(3-methoxybenzyl) thiourea differs from 1,3-di(4-methoxybenzyl)-thiourea structurally in that 1,3-di(3-methoxybenzyl) thiourea has the methoxy group present on its two benzene rings in the meta position, whereas 1,3-di(4-methoxybenzyl)-thiourea has the methoxy group present on its benzene rings in the para position. As is discussed in detail below, this structural difference between these two compounds results in these compounds having different chemical properties. Most significant in connection with the rejected claims of the patent application is that, in comparison with 1,3-di(3-methoxybenzyl) thiourea, 1,3-di(4-methoxybenzyl)thiourea is significantly less soluble in lipids and oils and, as a result, has a significantly decreased ability to enhance the oxidative stability of a lipid or oil to which the compound is added.

The less soluble a substituted thiourea compound is in a lipid or oil to which the compound is added, the less the compound will have the ability to enhance the oxidative stability of the lipid or oil (because more of it remains in an undissolved state).

I conducted the experiments described below in order to compare the solubility of 1,3-di(4-methoxybenzyl)thiourea and 1,3-di(3-methoxybenzyl) thiourea in refined meadowfoam seed oil. From these experiments, it can be seen that the solubility of 1,3-di(4-methoxybenzyl) thiourea in refined meadowfoam seed oil is, at most, 25% (one fourth) of the solubility of 1,3-di(3-methoxybenzyl) thiourea in refined meadowfoam seed oil, and is probably less. Thus, 1,3-di(3-methoxybenzyl) thiourea is three times more effective as an agent to enhance the oxidative stability of a lipid or an oil to which it is added in comparison with 1,3-di(4-methoxybenzyl)thiourea." [Emphasis added.]

Pages 8-9

". . . Further, the only compound described by the Johns et al. reference in its thirteen pages that has any similarity to the compounds described in the rejected claims is 1,3-di(4-methoxybenzyl)thiourea. However, experiments that I performed (described hereinabove) show that 1,3-di(4-methoxybenzyl)- thiourea is not very soluble in lipids and oils and, thus, is not effective as an agent to enhance the oxidative stability of a lipid or an oil to which the compound is added. Thus, the Johns et al. reference would not have suggested that the compounds described by rejected claims 1, 4, 7-9 and 10 of the application would have a reasonable likelihood of success in enhancing the oxidative stability of lipids or oils to which the compounds are added." [Emphasis added.]

The experiments that Dr. Abbott performed are described on pages 7-8 of this Declaration.

As another example, Dr. Abbott states (page 13) in this Declaration that it is his opinion as an expert in the area of thiourea compounds that, for the reasons that he presents in the declaration, 1-(3-methoxybenzyl)-3-methyl-2-thiourea differs from N-p-methoxybenzyl-N'-methylthiourea structurally, and likely in its chemical properties. In this regard, he makes the following statements (pages 13-14):

> "Further, the only compound described by the '089 patent that has any similarity to the compounds described in the rejected claims is N-p-methoxybenzyl-N'-methylthiourea. The compound encompassed within the rejected claims that is the most similar to N-p-methoxybenzyl-N'-methylthiourea is 1-(3-methoxybenzyl)-3-methyl-2-thiourea. 1-(3-methoxybenzyl)-3-methyl-2-thiourea differs from N-p-methoxybenzyl-N'-methylthiourea structurally, and likely in its chemical properties.
>
> 1-(3-methoxybenzyl)-3-methyl-2-thiourea differs from N-p-methoxybenzyl-N'-methylthiourea structurally in that the methoxybenzyl group present on the benzene ring is in the meta position, whereas N-p-methoxybenzyl-N'-methylthiourea has the methoxy group present on its benzene rings in the para position. Based upon the experiments that are presented hereinabove in Section 10 of this Declaration, and which involve a similar set of circumstances, I would predict that the structural difference between these two compounds would result in these compounds having different chemical properties. Based upon these experiments, I would predict that N-p-methoxybenzyl-N'-methylthiourea, in comparison with 1-(3-methoxybenzyl)-3-methyl-2-thiourea, would be significantly less soluble in lipids and oils and, as a result, have a significantly

decreased ability to enhance the oxidative stability of a lipid or oil to which the compound is added. . . " [Emphasis added.]

In conclusion, for the reasons set forth by Applicants above, Applicants submit that independent claim 1, and dependent claims 2, 5, 37 and 39, are each nonobvious under 35 U.S.C. §103. [See In re Fine, *supra*.]

In view of the amendments and discussion presented by Applicants hereinabove, the examiner is respectfully requested to withdraw the rejection of independent claim 1, and of dependent claims 2, 5, 37 and 39, of the application over claims 7 and 8 of the '628 patent (under a "statutory type" double patenting basis and/or under an "obviousness type" double patenting basis).

2. Rejection of Claims 11-14 and 18-32 under 35 U.S.C. §101

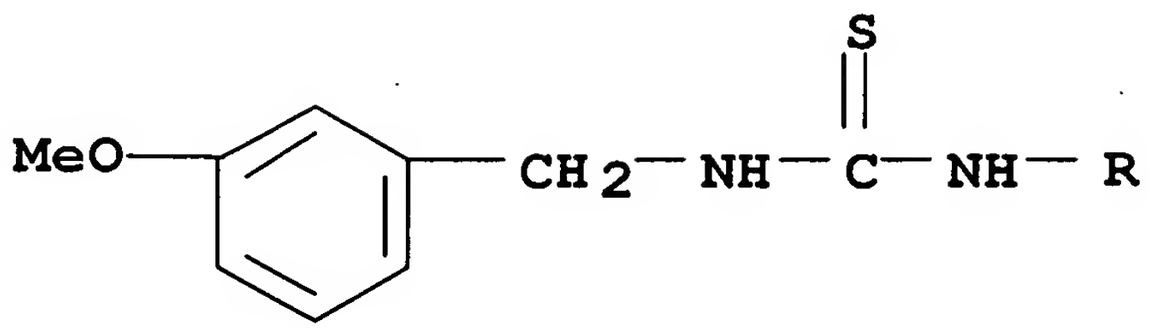
In the office action (page 2), the examiner rejected claims 11-14 and 18-32 under 35 U.S.C. §101 (a statutory type double patenting rejection) as "claiming the same invention as that of claims 16-19 of prior U.S. Patent No. 6,545,052."

For the reasons set forth below, Applicants respectfully submit that claims 11-14, 18 and 20-32 of the application, as these claims have been amended in the amendments set forth hereinabove, do not claim the same invention as that of claims 16-19 of U.S. Patent No. 6,545,052 ("the '052 patent") under 35 U.S.C. §101. Thus, Applicants traverse this claim rejection, and request that it be withdrawn.

The Rejected Claims

Claims 11-14, 18 and 20-32 of the application, as they have been amended in the amendments set forth hereinabove, are set forth below. Claim 19 has been canceled in the amendments set forth hereinabove and, thus, is not set forth below. Claim 11 is an independent claim, and claims 12-14, 18 and 20-32 are each dependent claims that ultimately depend upon claim 11.

11. A composition comprising a base lipid or oil supplemented with an oxidative stability-enhancing amount of a compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, a C_5 - C_7 cycloalkyl, an alkoxy-substituted C_5 - C_7 cycloalkyl, a hydroxy-substituted C_5 - C_7 cycloalkyl, a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl, and wherein the composition has a greater oxidative stability than an oxidative stability of the base lipid or oil prior to supplementation with the compound, with the proviso that the compound is not 1,3-di(3-methoxybenzyl) thiourea.

12. A composition of Claim 11 wherein R is a C_1 - C_{20} linear or branched alkyl.

13. A composition of Claim 11 wherein R is a C_5 - C_7 cycloalkyl, an alkoxy-substituted C_5 - C_7 cycloalkyl or a hydroxy-substituted C_5 - C_7 cycloalkyl.

14. A composition of Claim 11 wherein R is a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl.

18. A composition of Claim 14 wherein the compound is 1-(3-methoxybenzyl)-3-ethyl-2-thiourea, 1-(3-methoxybenzyl)-3-propyl-2-thiourea, 1-(3-methoxybenzyl)-3-hexyl-2-thiourea, 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea, 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea or 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea.

20. A composition of Claim 11 wherein the base lipid or oil is a seed oil or vegetable oil.

21. A composition of Claim 11 wherein the base lipid or oil is meadowfoam oil, peanut oil, corn oil, cottonseed oil, safflower oil, soybean oil, high oleic sunflower oil,

milkweed seed oil, rapeseed oil, palm oil, olive oil, jojoba wax ester, jojoba oil, lecithin or another vegetable oil.

22. A composition of Claim 21 wherein the base lipid or oil is jojoba oil, meadowfoam oil, high oleic sunflower oil, soybean oil or milkweed seed oil, and wherein the base lipid or oil is supplemented with from about 0.1 wt. % to about 1.0 wt. % of the compound.

23. A composition of Claim 11 wherein the base lipid or oil contains one or more benzylamine or N-substituted benzylamine compounds.

24. A composition of Claim 23 wherein the base lipid or oil is meadowfoam seed oil.

25. A composition of Claim 11 wherein the base lipid or oil is also supplemented with an oxidative stability-enhancing amount of one or more benzylamine or N-substituted benzylamine compounds.

26. A composition of Claim 11 wherein the composition exhibits an Oxidative Stability Index value of at least about 10% greater than an Oxidative Stability Index value of the base lipid or oil prior to supplementation with the compound when an Oxidative Stability Index test is carried out at a temperature between about 110°C and about 130 °C.

27. A composition of Claim 26 wherein the composition exhibits an Oxidative Stability Index value of at least about 100% greater than the Oxidative Stability Index value of the base lipid or oil.

28. A composition of Claim 27 wherein the composition exhibits an Oxidative Stability Index value of at least about 200% greater than the Oxidative Stability Index value of the base lipid or oil.

29. A composition of Claim 28 wherein the composition exhibits an Oxidative Stability Index value of at least about 500% greater than the Oxidative Stability Index value of the base lipid or oil.

30. A composition of Claim 29 wherein the composition exhibits an Oxidative Stability Index value of at least about 800% greater than the Oxidative Stability Index value of the base lipid or oil.

31. A composition of Claim 30 wherein the composition exhibits an Oxidative Stability Index value of at least about 1,000% greater than the Oxidative Stability Index value of the base lipid or oil.

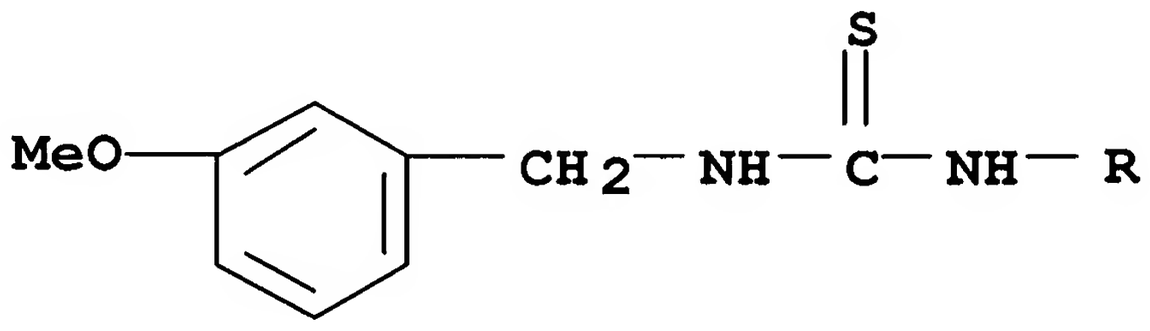
32. A composition of Claim 31 wherein the composition exhibits an Oxidative Stability Index value of at least about 1,500% greater than the Oxidative Stability Index value of the base lipid or oil.

Claims 16-19 of U.S. Patent No. 6,545,052 B2

Claims 16-19 of U.S. Patent No. 6,545,052 B2 are set forth below. Although claim 15 was not rejected, because claims 17-19 depend upon claim 15, claim 15 is also set forth below.

15. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

I

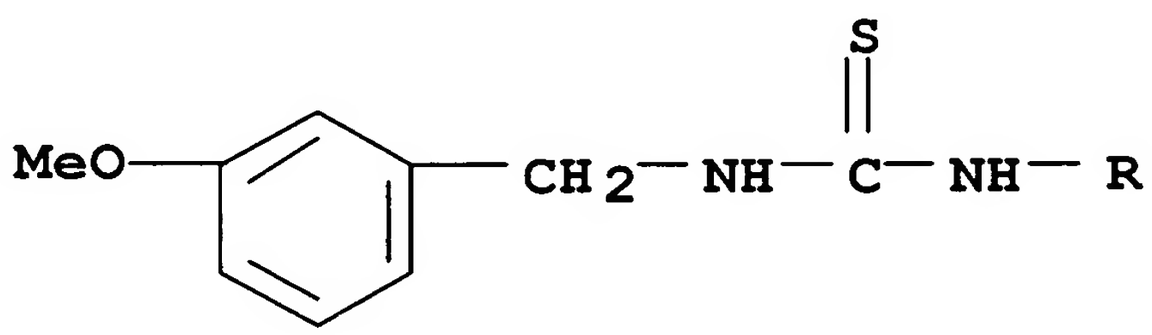


wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 -

C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition, and wherein the composition further comprises a sunscreen compound in a concentration effective for sunscreen protection.

16. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

I



wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition and wherein the composition of formula I is 1,3-di(3-methoxybenzyl) thiourea.

17. A composition according to claim 15 wherein the base composition comprises an oil that contains the compound of formula I.

18. A composition according to claim 17 wherein the composition is an emulsion.

19. A composition according to claim 17 wherein the oil is meadowfoam seed oil.

Argument

"Statutory Type" Double Patenting

For the reasons set forth hereinbelow, Applicants respectfully submit that claims 11-14, 18 and 20-32 of the application, as these claims have been amended in the amendments set forth hereinabove, do not claim the same invention as that of claims 16-19 of the '052 patent under 35 U.S.C. §101.

A comparison of claims 11-14, 18 and 20-32 of the application, as they have been amended, with claims 16-19 of the '052 patent clearly shows that the "same" invention is not being claimed twice between any of the rejected claims and any of claims 16-19 of the '052 patent (i.e., none of the rejected claims are identical in scope with any of claims 16-19 of the '052 patent).

Claims 17, 18 and 19 of the '052 patent each include a limitation stating that, "wherein the composition further comprises a sunscreen compound in a concentration effective for sunscreen protection." This limitation is not present in any of claims 11-14, 18 or 20-32 of the present application. Thus, claims 11-14, 18 and 20-32 of the present application could be literally infringed without infringing any of claims 17, 18 or 19 of the '052 patent.

Further, claim 16 of the '052 patent contains a limitation stating that, "wherein the compound of formula I is 1,3-di(3-methoxybenzyl)thiourea." In contrast, claim 11 of the present application has been amended in the amendments set forth above to add a proviso thereto that states, "with the proviso that the compound is not 1,3-di(3-methoxybenzyl) thiourea." Further, dependent claim 18 has been amended to delete therefrom the compound 1,3-di(3-methoxybenzyl) thiourea, and claim 19 has been canceled. Thus, claim 16 of the '052 patent could be literally infringed without infringing claim 11 of the present application (or dependent claims 12-14, 18 or 20-32).

Applicants submit that the addition of the above-described proviso to claim 11 of the application does not constitute new matter because such an addition has the effect of narrowing, not broadening, the invention that is claimed in this claim (excluding a

compound that was encompassed within Applicants' originally-filed claims). The examiner is referred to the discussion set forth hereinabove under "1. Rejection of Claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101" regarding In re Johnson and Farnham, *supra*. and In re Driscoll, *supra*, which is incorporated herein by reference in its entirety.

Like the facts in In re Johnson and Farnham, Applicants originally-filed specification contains a broad and complete generic disclosure, coupled with examples that are fully supportive of the invention claimed in amended claim 11, and Applicants have narrowed, rather than broadened, claim 11, with the full scope of the claimed invention being supported by the originally-filed specification, generically and by examples.

If the examiner takes the position that the amendment to claim 11 constitutes new matter, Applicants respectfully request that the examiner provide for Applicants the citations to the statutory, regulatory and/or case law that is used to support the examiner's position.

"Obviousness Type" Double Patenting

The examiner has not rejected claims 11-14 or 18-32 over claims 16-19 of the '052 patent under the judicially created doctrine of "obviousness type" double patenting. Nevertheless, Applicants have also addressed this issue.

For the reasons set forth below, Applicants respectfully submit that a *prima facie* case of obviousness of the subject matter that is described in claims 11-14, 18 and 20-32 of the application, as amended in the amendments set forth hereinabove, over the subject matter that is described in claims 16-19 of the '052 patent, has not been established. Applicants submit that the subject matter that is described in claims 11-14, 18 and 20-32 of the application is patentably distinguished from the subject matter that is described in claims 16-19 of the '052 patent (i.e., that none of claims 11-14, 18 and 20-32 of the application defines merely an obvious variation of the subject matter that is described in claims 16-19 of the '052 patent).

First, Applicants respectfully submit that several structural, chemical and other differences exist between the subject matter that is described in claims 11-14, 18 and 20-32 of the application, as these claims have been amended hereinabove, and the subject

matter that is described in claims 16-19 of the '052 patent, and that such differences are such that the subject matter described in claims 11-14, 18 and 20-32 of the application as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Further, for the reasons set forth hereinbelow, Applicants submit that the subject matter that is described in claims 16-19 of the '052 patent would not have suggested the invention that is described in claims 11-14, 18 and 20-32 of the application to one of ordinary skill in the art.

Claim 11 of the application (and claims 12-14, 18 and 20-32, which depend upon claim 11) contains:

(a) a limitation that the base lipid or oil described therein is supplemented "with an oxidative stability-enhancing amount" of a compound set forth therein;

(b) a limitation stating, "wherein the composition has a greater oxidative stability than an oxidative stability of the base lipid or oil prior to supplementation with the compound"; and

(c) a new proviso stating, "with the proviso that the compound is not 1,3-di(3-methoxybenzyl) thiourea."

Moreover, dependent claims 22-32 of the application contain many additional limitations.

Applicants respectfully submit that none of the above-described limitations that are present in independent claim 11 (and claims 12-14, 18 and 20-32, which depend upon claim 11), or in dependent claims 22-32, of the application are taught or suggested by any of claims 16, 17, 18 or 19 of the '052 patent. None of these claims discusses anything about an enhancement of an oxidative stability of a lipid or oil. These claims are directed to compositions that perform a completely different function (an inhibition of free radical degradation in skin and hair), which is clearly indicated by limitations that are present in each of these four claims.

Further, claim 16 of the '052 patent is limited to a composition that contains one specific compound, which is 1,3-di(3-methoxybenzyl) thiourea. In contrast, claims 11, 18 and 19 of the application (and claims 12-14 and 20-32, which depend upon claim 11) have each been amended in the amendments set forth above to remove the compound 1,3-di(3-methoxybenzyl) thiourea from these claims. Thus, the compounds that are

described in claims 11-14, 18 and 20-32 of the application are structurally different from the compound that is described in claim 16 of the '052 patent.

Applicants respectfully submit that the differences that exist between the compounds that are described in claims 16-19 of the '052 patent and the rejected claims are patentable differences.

As is discussed hereinabove, the disclosure of the '052 patent cannot be employed in support of a double patenting rejection. Thus, claims 16-19 of the '052 patent do not teach or suggest all claim limitations, as is required to establish a *prima facie* case of obviousness.

Further, because claims 16-19 of the '052 patent describe (in the claims themselves) a completely different effect of the compositions described therein (an inhibition of free radical polymerization in skin and hair) in comparison with the effect that is described in the rejected claims of the application (an enhancement of an oxidative stability of a base lipid or oil), claims 16-19 of the '052 patent do not provide a motivation for one of ordinary skill in the art to make the compositions that are described in claims 11-14, 18 and 20-32 of the application.

In view of the discussion above, it is clear that claims 16-19 of the '052 patent would not have suggested the invention that is described in claims 11-14, 18 and 20-32 of the application to one of ordinary skill in the art.

Assuming arguendo that it would have been obvious to try to prepare the compositions that are described in claims 11-14, 18 and 20-32 of the application in view of claims 16-19 of the '052 patent, which Applicants submit that is was not, the Federal Circuit has held that "obvious to try" is not the standard under §103. [In re O'Farrell, *supra*.]

Second, for the reasons set forth below, Applicants respectfully submit that the subject matter that is described in claims 16-19 of the '052 patent would not have suggested that the invention that is described in claims 11-14, 18 and 20-32 of the application would have a reasonable likelihood of success.

In his enclosed second Declaration, Dr. Abbott states that it is his opinion as an expert in the area of thiourea compounds that, for the reasons set forth therein, the subject matter that is described in claims 1-21 of the '052 patent would not have suggested that

the invention that is described in any of claims 1, 4, 7-36, 40 and 41 of the application (as these claims have been amended in an accompanying amendment and response to the office action) would have a reasonable likelihood of success.

Moreover, as is discussed hereinabove, a significant amount of unpredictability exists in the art of disubstituted thiourea compounds, to which the compositions that are described in claims 11-14, 18 and 20-32 of the application are directed. The examiner is referred to the discussion set forth by Applicants hereinabove under "1. Rejection of Claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101" regarding the unpredictability that exists with disubstituted thiourea compounds, which is incorporated herein by reference in its entirety (including the entireties of the first and second declarations that have been submitted by Dr. Thomas P. Abbott).

In his enclosed second Declaration, Dr. Abbott states that a significant amount of unpredictability exists in the art of disubstituted thiourea compounds, to which claims 1, 4, 7-36, 40 and 41 of the application are directed (disubstituted thiourea compounds, compositions containing these compounds and methods of using these compounds). Dr. Abbott discusses the fact that thiourea compounds that may appear to have similar chemical structures may have very different chemical properties (i.e., that unpredictability exists in this area). Dr. Abbott states that, as a polymer chemist, he is aware of a number of systems in which small differences in chain length of additives produce dramatic differences in compatibility with a polymer system, and provides examples of such systems. He further states that dispersibility and water, polymer and/or solvent solubility change dramatically and unpredictably with sidechain length for many different structures and applications, including disubstituted thioureas. Thus, he states that it is generally true that in polymer systems, or in lipids and/or oils, additives may have dramatically different effects with even small changes of one or two carbons in sidechain length, and that these effects are often surprising and unexpected. For example, he states that a disubstituted thiourea that has a low solubility in lipids and oils may have a significantly decreased ability to enhance the oxidative stability of a lipid or oil to which the compound is added.

Moreover, in his first Declaration, Dr. Abbott also discusses the fact that thiourea compounds that may appear to have similar chemical structures may have very different chemical properties (i.e., that unpredictability exists in this area).

Further, Applicants submit that there is no teaching, suggestion or other indication from claims 16-19 of the '052 patent (with or without the use of the disclosure, which is prohibited) that the compositions that are described in claims 11-14, 18 and 20-32 of the application would have an ability to successfully enhance the oxidative stability of a base lipid or oil to which the compositions are added (a limitation that is present in each of these claims). Claims 16-19 of the '052 patent do not discuss an enhancement of an oxidative stability of a base lipid or oil and, in fact, describe a completely different application for the compositions described therein. Claims 16-19 of the '052 patent each describe an inhibition of free radical degradation of skin or hair of a human or nonhuman animal.

In his enclosed second Declaration, Dr. Abbott states that it is clear from a review of claims 1-21 of the '052 patent and claims 1, 4, 7-36, 40 and 41 of the application that the problems that the inventors of the invention described in the '052 patent were attempting to solve are completely different from the problem with which the inventors of the invention described in the rejected claims of the present patent application were concerned.

Further, in his second Declaration, Dr. Abbott states that the chemical mechanisms for inhibiting free radical degradation of the skin or hair of a human or nonhuman animal and related properties are substantially different from the chemical mechanisms for enhancing an oxidative stability of a lipid or oil to which a disubstituted thiourea compound has been added. The examiner is referred to the detailed discussion following this statement in the second Declaration.

Moreover, in the second Declaration, Dr. Abbott discusses an article entitled, "Review, The Problems of Using One-Dimensional Methods to Evaluate Multifunctional Food and Biological Antioxidants" (Edwin N. Frankel et al., Journal of the Science of Food and Agriculture 80, 1925-1941, 2000), which is enclosed for the examiner's review, the authors of which are leading world experts in antioxidants. Dr. Abbott states in the Declaration that, in this article, the authors describe the unpredictable nature of

antioxidant activity and a variety of factors that influence antioxidant activity, including the type of substrate and the temperature of the testing conditions, and show that the effectiveness of antioxidants is strongly dependent on the test system, the physical states of the lipid substrates, the conditions of oxidation, the oxidizing substrate, the localisation of antioxidants and the method employed to evaluate oxidation and the stages of oxidation.

In his second Declaration, Dr. Abbott states that, in the above-described paper, the authors also demonstrate that the difference between the testing of a bulk oil medium at a high temperature (as is described in the patent application) and a free radical inhibitor present in aqueous media (as is described in the '052 patent) leads to different results, and to different applications, for antioxidants. Dr. Abbott states that, on pages 1928-1930 of this article, the authors describe the reversal of ranking or elimination of antioxidant activity when tests are conducted in aqueous emulsions as compared to activity in bulk oils.

Dr. Abbott states his declaration that, regarding the above issues, the above article makes the following statements at the locations indicated:

> **Abstract**
>
> "The activity of antioxidants in foods and biological systems is dependent on a multitude of factors, including the colloidal properties of the substrates, the conditions and stages of oxidation and the localisation of antioxidants in different phases. When testing natural antioxidants in vitro, it is therefore important to consider the system composition, the type of oxidisable substrate, the mode of accelerating oxidation, the methods to assess oxidation and how to quantify antioxidant activity. Antioxidant effectiveness is also determined by the heterogeneity and heterophasic nature of the system, the type of lipid substrate, including its physiochemical state and degree of unsaturation, the types of initiators, notably transition metals, other components and their possible interactions. For this reason, there cannot be a short-cut approach to determining antioxidant activity. Each evaluation should be carried out under various conditions of oxidation, using several methods to measure different products of oxidation. . . Several recent studies on natural phytochemical compounds produced conflicting results because non-specific and one-dimensional methods were used to evaluate antioxidant activity. There is a great need to standardise antioxidant testing to minimize the present chaos in the methodologies used to evaluate antioxidants. . ." [Emphasis added.]

Page 1925

". . . Although there is a great multiplicity of methods used for antioxidant testing, there are no approved, standardised methods. Several rapid test methods to screen for antioxidant activity have been published and many different in vitro antioxidant protocols are currently used to evaluate antioxidants of interest in food and nutrition, health and disease. Obviously, the significance and relevance of antioxidant evaluations for food and biological systems depend strongly on the test method. Inconsistent results have been obtained for a number of recognised antioxidants depending on the methods used to test activity."

Pages 1926-1927

". . . Misleading data can be obtained in many of these test systems by neglecting important compositional and interfacial phenomena concerning charge and solubility of multiple components in real food or biological systems that strongly affect antioxidant performance.

. . . The effectiveness of antioxidants in complex heterogeneous foods and biological systems and in multiphase models is affected by many factors. Notable factors include the partitioning properties of the antioxidants between lipid and aqueous phases, the oxidation conditions and the physical state of the oxidisable substrate. Clearly, the influence of all relevant parameters cannot be evaluated by using only a one-dimensional assay protocol. Of particular importance are the conditions used to accelerate oxidation by raising the temperature, by using transition metal catalysts or other types of initiators, by increasing surface and by exposing to light of varying intensity." [Emphasis added.]

Page 1928

"Antioxidant action becomes more complex in real foods and biological systems where a variety of mechanisms become effective, including free radical chain breaking, oxygen scavenging, singlet oxygen quenching, metal chelation and inhibition of oxidative enzymes. . . Meaningful interpretation of antioxidant action requires specifying the oxidising substrate protected by the putative antioxidant . . .

. . . The activity of different types of antioxidants can vary significantly depending on whether the lipids are triacylglycerols, methyl esters, free fatty acids or incorporated into various biological particles such as lipoproteins or liver microsomes. Whether the antioxidants function in aqueous, bulk lipid or in heterophasic systems is critically important." [Emphasis added.]

Page 1929

". . . The phenomenological observation that polar antioxidants are more active in bulk oil systems whereas non-polar antioxidants are more active in lipid suspended in aqueous systems was referred to as the 'polar paradox' by Porter. . . This interfacial phenomenon was explained by differences in the affinity of hydrophilic and lipophilic antioxidants towards the air, oil and water phases as well as the interface. . ." [Emphasis added.]

Pages 1929-1930

". . . The partitioning properties of a particular antioxidant not only depend on the chemical structure and relative polarity of the antioxidant, but also vary according to the lipid substrates, surfactants, pH, temperature and the composition of the phases. . .

In summary, antioxidant effectiveness in multiphase food and biological systems is affected by important factors determined by interfacial phenomena governing the localisation and orientation of antioxidants by partitioning between the aqueous phase and the lipophilic phase and by interacting with the emulsifier at the interface. . . More knowledge is required on the partitioning behavior and efficiency of antioxidants in different phases to improve our understanding of antioxidant properties in different colloidal food and biological systems.

. . . The relative activity of various antioxidants depends on the type of substrate (eg phospholipid vs triacylglycerols and free fatty acids), the degree of lipid unsaturation and the physiochemical state of the oxidizable substrate. Some of the observed differences are attributable to the degree of heterogeneity of the system as discussed above, and complicated by the colloidal properties of the lipid substrate. . .

. . . In contrast to triacylglycerols, linoleic acid forms micelles in aqueous systems, which have different colloidal properties strongly affecting the behavior of both oxidation initiators and antioxidants." [Emphasis added.]

Pages 1931-1932

"Many examples in the literature show that phenolic compounds can have either antioxidant activity or prooxidant activity depending on the oxidizing target and conditions used in the test system. A number of examples illustrate the variation in activity of antioxidants tested in different lipid systems (Table 3). Hydrophilic polyphenolic compounds showed significantly different trends in antioxidant activity when tested in three different systems. . .

The antioxidant effectiveness of rosemary extracts, carnosol and carnosic acid, was significantly influenced by the type of system tested,

the oil substrates, the methods used to follow oxidation, and the concentrations of test compounds. Although the rosemary extracts and compounds effectively inhibited oxidation in corn oil, soybean oil, peanut oil and fish oil, when tested in bulk, these compounds were either inactive or promoted oxidation in the corresponding vegetable oil-in-water emulsion. . .

In conclusion, the structure-activity relationship of natural phenolic antioxidants is not only significantly affected by the test system used and the biological targets to be protected, but also by the modes of inducing oxidation and by the method used to determine oxidation.* Antioxidant activity may be further modulated by other components present in the test system." [Emphasis added.]

*Dr. Abbott states in his second Declaration that this statement would apply to all antioxidants, not just to phenolics.

Page 1937

". . . These data emphasize that the ranking of antioxidant activity is strongly dependent on the test system and on the substrate to be protected by the antioxidants. . .

RECOMMENDED PROTOCOLS

We have seen in this survey that the effectiveness of antioxidants is strongly dependent on the test system, the physical states of the lipid substrates, the conditions of oxidation, the oxidizing substrate, the localisation of antioxidants and the method employed to evaluate oxidation and the stages of oxidation. . .

. . . Various testing protocols should consider the following parameters. . .

(1) Substrates. Use substrates relevant to foods and biological systems. . . Free fatty acids should be avoided because they form miscelles in which antioxidants behave differently than in triacylglycerols.

(2) Conditions. Test under various conditions, including different temperatures (below 60°C), metal catalysts and surface exposures. Select conditions to simulate real food or biological systems as closely as possible, depending upon the application. . .

In biological systems, phenolic compounds can participate in several antioxidant defences, including preventing oxidant formation, scavenging activated oxidants, reducing active intermediates and inducing repair systems. To improve our understanding of these complex interactions in different systems, the use of non-specific and one-dimensional assays for anti-oxidant capacity would be risky because they do not provide information on the biological target(s) protected. . .

> CONCLUSIONS
>
> . . . When testing antioxidant activity of potential food antioxidants or bioactive compounds, the first aim may be to develop a model system where basic chemical principles can be deduced. On the other hand, the true effectiveness of antioxidants cannot be properly assessed unless the conditions, ie the complexity of the system, are as close as practically possible to the conditions under which protection against autoxidation is required. Targeting of antioxidants to prevent particular free radical formation steps and oxidative deterioration processes requires detailed understanding of the mechanisms of oxidation. Specific lipid model systems should mimic the food or physiological target systems to be protected as close as practically possible. There are various sources and types of oxidation and we should first define the targets of oxidation - lipids, protein, DNA-before selecting methods to assess the protective properties of antioxidants under the conditions of their potential action and use. . . In view of the wide divergence of results of natural antioxidants in foods and biological systems, more valid guidelines and assay protocols are urgently needed to bring some order to the present chaos in this important field. Our understanding of the effects of antioxidant compounds can only be improved if more specific methodology is used capable of defining what products are formed and inhibited by antioxidants depending upon conditions, systems and targets of protection." [Emphasis added.]

In his second Declaration, Dr. Abbott states that, another article (copy enclosed) entitled, "Lipid Oxidation: Mechanisms, Products and Biological Significance" (E. N. Frankel, J. Am. Oil Chem. Soc. Vol. 61, No. 12, 1908-1917, 1984) contains (page 1915) numerous examples of biological damage that can be caused to proteins by free radicals. He states that, in yet another article (copy enclosed) entitled "Chemistry of Free Radical and Singlet Oxidation of Lipids," (E. N. Frankel, Prog. Lipid Res. 23, 197-221, 1985), the same author reviews structural studies of primary and secondary products of lipid oxidation, and states (page 197) that the decomposition products are implicated in many in vivo biological processes. Dr. Abbott states that this author points out (page 213) that high molecular weight products of lipid oxidation occur in high yields, and (page 219) that the levels of low molecular weight products are small compared to the "1 to 8%" of "mainly polymeric" substances generated by free radical attack.

In his second Declaration, Dr. Abbott also states that the OSI test that is described in the present application measures specifically the low molecular weight breakdown

products of oxidation of lipids. In contrast, he states that the test described in the '052 patent measures the prevention of the formation of high molecular products by free radical crosslinking of protein in skin and hair.

Dr. Abbott further states in his second Declaration that any one of the compounds or compositions that are described in the rejected claims of the application may have additional properties or applications as yet undiscovered. For example, he states that it is well established that natural products having cellular reproductive inhibition in the brine shrimp assay as described in Abbott et al. (Industrial Crops and Products 16, 46-53 (2002)) may also inhibit cancer cells and have therapeutic value. He states that some of the compounds that have been determined to be most effective in the present application, such as 1,3-di(3-methoxybenzyl) thiourea, were determined to be the least effective in cellular inhibition in the above-cited Abbott et al. publication. He states that the same logic should be applied to the free radical inhibition in hair and skin compared with oxidative stability enhancement.

Dr. Abbott further states in his second Declaration that the subject matter that is described in the rejected claims of the present application is different in both the mechanism of action, and the substrate on which it acts, in comparison with the subject matter that is claimed in the '052 patent. He states that, preventing damage to hair and skin by free radicals is accomplished by reacting with high energy free radicals, specifically reactive oxygen species, as is described in the Background of the Invention section of the '052 patent. He further states that enhancing antioxidative effects in oils with the addition of the compounds and compositions that are described in the rejected claims of the application, in contrast, is accomplished by decomposing hydroperoxy derivatives of the oils, before the oils proceed to the next step to decomposition to aldehydes and acids.

Applicants have enclosed another article for the examiner's review entitled, "Kinetic Studies of Petroleum Antioxidants," G.W. Kennerly et al., Industrial and Engineering Chemistry, Vol. 48, No. 10, 1917-1924 (1956), which clearly differentiates between the free radical and hydroperoxide decomposition mechanisms for sulfur-containing antioxidants in hydrocarbons.

In conclusion, Applicants submit that independent claim 11, and dependent claims 12-14, 18 and 20-32, of the application are each nonobvious under 35 U.S.C. §103. [See In re Fine, *supra*.]

In view of the amendments and discussion presented by Applicants hereinabove, the examiner is respectfully requested to withdraw the rejection of independent claim 11, and of dependent claims 12-14, 18 and 20-32, of the application over claims 16-19 of the '052 patent (on a "statutory type" double patenting basis and/or on an "obviousness type" double patenting basis).

3. **Rejection of Claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 under the Doctrine of Obvious-Type Double Patenting**

In the office action (page 3), the examiner rejected claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,545,052 ("the '052 patent"). The examiner stated that, although the conflicting claims are not identical, they are not patentably distinct from each other because the compound/composition as presently claimed is used in the method claims of the '052 patent. The examiner also stated that, "And it is not understood, by the Examiner, why the present compound/composition claims where [were] not filed (claimed) along with the method claims of the application, which is now US Pat. 6,545,052."

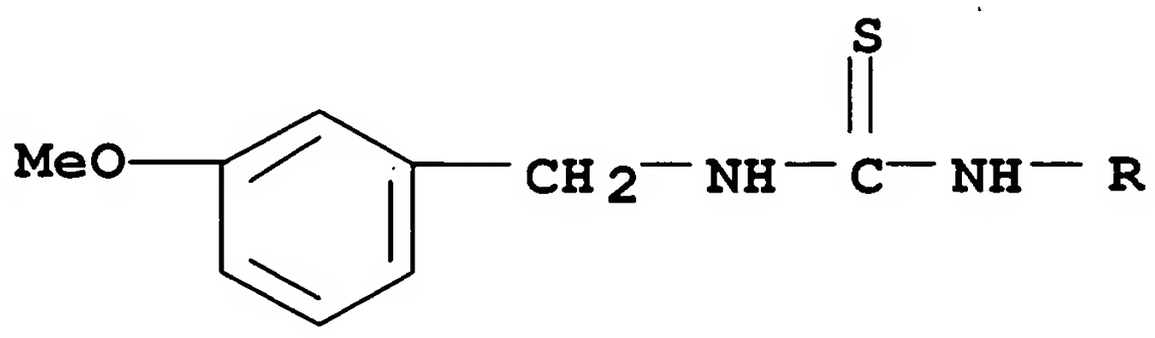
For the reasons set forth below, Applicants respectfully submit that the subject matter that is described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application, as these claims have been amended in the amendments set forth hereinabove, is not obvious over, and is patentably distinct from, the subject matter that is described in claims 1-21 of the '052 patent. Thus, Applicants traverse this claim rejection, and request that it be withdrawn.

The Rejected Claims

Claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application, as they have been amended in the amendments set forth hereinabove, are set forth below. Claim 1 is an independent claim, and claims 4, 7-10, 40 and 41 are dependent upon claim 1. Claim 11

is also an independent claim, and claims 15-17 are dependent upon claim 11. Claim 33 is also an independent claim, and claims 34-36 are dependent upon claim 33.

1. A compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl, and wherein the compound enhances the oxidative stability of a lipid or oil to which the compound is added, with the proviso that R is not phenyl, octyl or octadecyl.

4. A compound of Claim 1 wherein R is a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl.

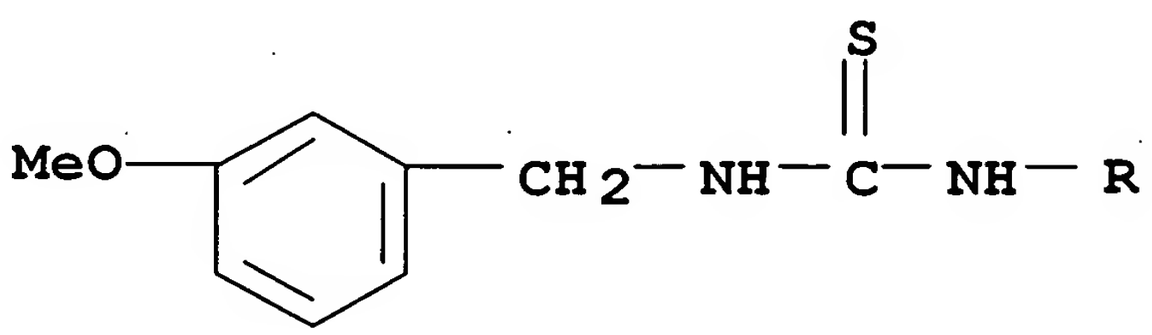
7. A compound of Claim 4 wherein R is benzyl, hydroxyphenyl, hydroxybenzyl, methoxyphenyl, ethoxyphenyl, methoxybenzyl or ethoxybenzyl.

8. A compound of Claim 4 wherein R is a 3-hydroxy-substituted or 3-alkoxy-substituted aryl moiety.

9. A compound of Claim 1 wherein the compound is 1,3-di(3-methoxybenzyl) thiourea, 1-(3-methoxybenzyl)-3-ethyl-2-thiourea, 1-(3-methoxybenzyl)-3-propyl-2-thiourea, 1-(3-methoxybenzyl)-3-hexyl-2-thiourea, 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea, 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea or 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea.

10. A compound of Claim 9 wherein the compound is 1,3-di(3-methoxybenzyl) thiourea.

11. A composition comprising a base lipid or oil supplemented with an oxidative stability-enhancing amount of a compound of the formula:



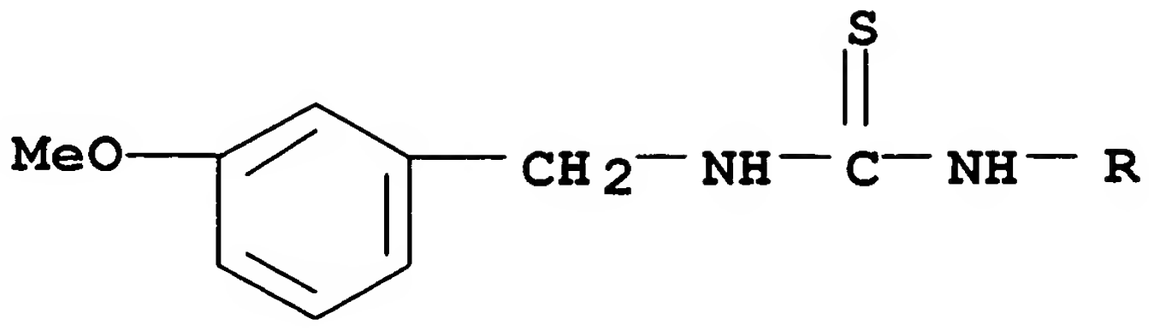
wherein R is a C_1 - C_{20} linear or branched alkyl, a C_5 - C_7 cycloalkyl, an alkoxy-substituted C_5 - C_7 cycloalkyl, a hydroxy-substituted C_5 - C_7 cycloalkyl, a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl, and wherein the composition has a greater oxidative stability than an oxidative stability of the base lipid or oil prior to supplementation with the compound, with the proviso that the compound is not 1,3-di(3-methoxybenzyl) thiourea.

15. A composition of Claim 11 wherein the base lipid or oil is supplemented with from about 0.01 wt. % to about 5.0 wt. % of the compound, based on the total weight of the base lipid or oil.

16. A composition of Claim 15 wherein the base lipid or oil is supplemented with from about 0.05 wt. % to about 2.0 wt. % of the compound.

17. A composition of Claim 16 wherein the base lipid or oil is supplemented with from about 0.1 wt. % to about 1.0 wt. % of the compound.

33. A method for enhancing the oxidative stability of a base lipid or oil comprising the step of combining the base lipid or oil with an oxidative stability-enhancing amount of compound of the formula:



wherein R is a C_1 - C_{20} linear or branched alkyl, a C_5 - C_7 cycloalkyl, an alkoxy-substituted C_5 - C_7 cycloalkyl, a hydroxy-substituted C_5 - C_7 cycloalkyl, a C_6 - C_7 aryl, a hydroxy-substituted C_6 - C_7 aryl or an alkoxy-substituted C_6 - C_7 aryl.

34. A method of Claim 33 wherein the base lipid or oil is combined with from about 0.05 wt. % to about 2.0 wt. % of the compound.

35. A method of Claim 34 wherein the compound is 1,3-di(3-methoxybenzyl) thiourea, 1-(3-methoxybenzyl)-3-ethyl-2-thiourea, 1-(3-methoxybenzyl)-3-propyl-2-thiourea, 1-(3-methoxybenzyl)-3-hexyl-2-thiourea, 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea, 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea or 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea.

36. A method of Claim 35 wherein the compound is 1,3-di(3-methoxybenzyl) thiourea.

40. A compound of Claim 7 wherein R is benzyl, hydroxyphenyl, hydroxybenzyl, methoxyphenyl, ethoxyphenyl or ethoxybenzyl.

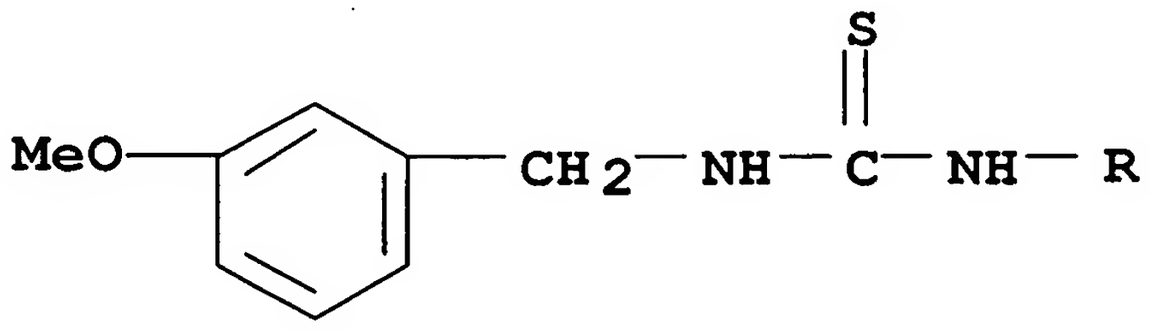
41. A compound of Claim 9 wherein the compound 1-(3-methoxybenzyl)-3-ethyl-2-thiourea, 1-(3-methoxybenzyl)-3-propyl-2-thiourea, 1-(3-methoxybenzyl)-3-hexyl-2-thiourea, 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea, 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea or 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea.

Claims 1-21 of U.S. Patent No. 6,545,052 B2

Claims 1-21 of the '052 patent are set forth below.

1. A method for inhibiting free radical degradation of skin or hair of a human or nonhuman animal comprising contacting the skin or hair with a composition comprising at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

(I)



in a concentration which is effective to inhibit free radical polymerization, wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl.

2. A method according to claim 1 wherein the composition comprises between about 0.01% and 5% by weight of the compound of formula I.

3. A method according to claim 2 wherein the composition comprises between about 0.1% and 2% by weight of the compound of formula I.

4. A method according to claim 1 wherein the compound of formula I is contained in an oil.

5. A method according to claim 4 wherein the composition is an emulsion.

6. A method according to claim 4 wherein the oil is meadowfoam seed oil.

7. A method according to claim 1 wherein R is selected from the group consisting of (i) C_1 - C_{20} linear alkyl, (ii) hydroxy-substituted C_6 - C_7 aryl and (iii) alkoxy-substituted C_6 - C_7 aryl moieties.

8. A method according to claim 1 wherein the compound of formula I is selected from the group consisting of 1,3-di(3-methoxybenzyl) thiourea; 1-(3-methoxybenzyl)-3-ethyl-2-thiourea; 1-(3-methoxybenzyl)-3-propyl-2-thiourea; 1-(3-methoxybenzyl)-3-hexyl-2-thiourea; 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea; 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea; and 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea.

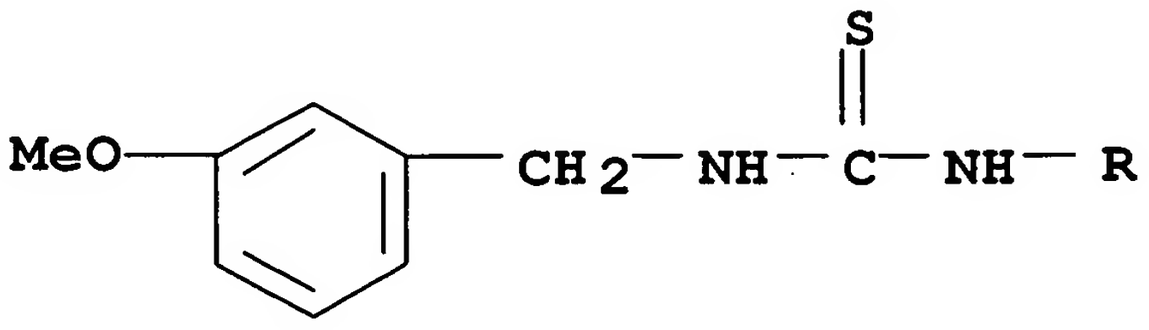
9. A method according to claim 1 wherein the compound of formula I is 1,3-di(3-methoxybenzyl) thiourea.

10. A method according to claim 1 wherein the composition inhibits the free radical degradation of the skin after contacting the composition with the skin.

11. A method according to claim 1 wherein the composition inhibits the free radical degradation of the hair after contacting the composition with the hair.

12. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

I

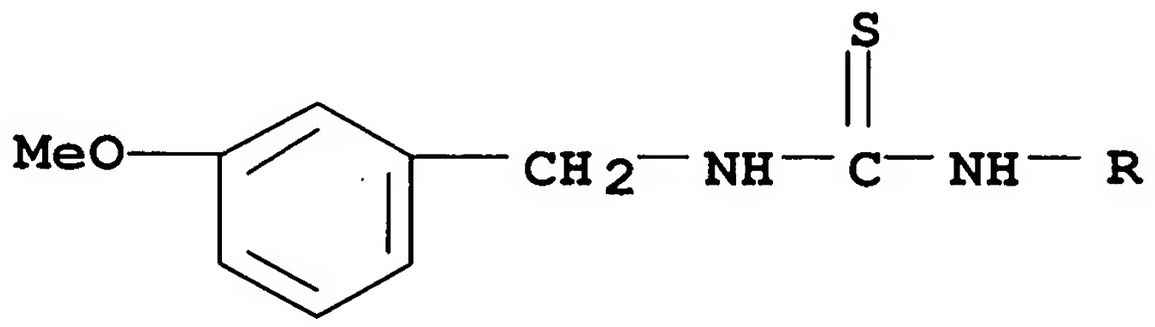


wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7

aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition, wherein the base composition comprises an oil that contains the compound of formula I and wherein the oil is meadowfoam seed oil.

13. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

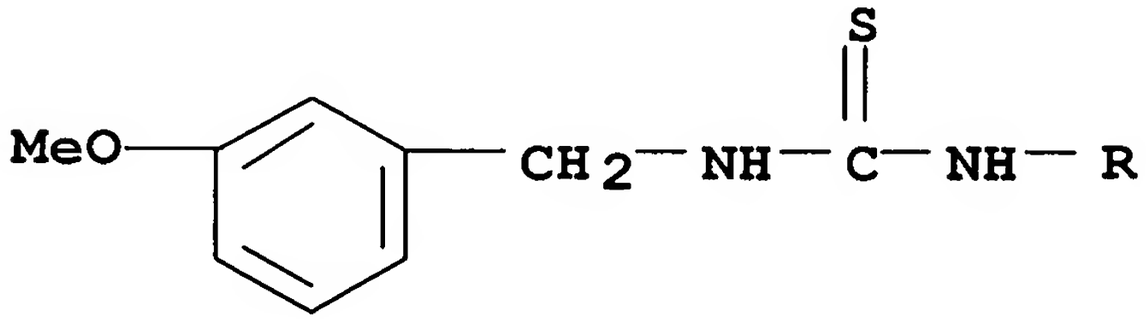
I



wherein R is selected from the group consisting of (i) C_1 - C_{20} linear alkyl; (ii) hydroxy-substituted C_6 - C_7 aryl and; (iii) alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, and wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition.

14. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

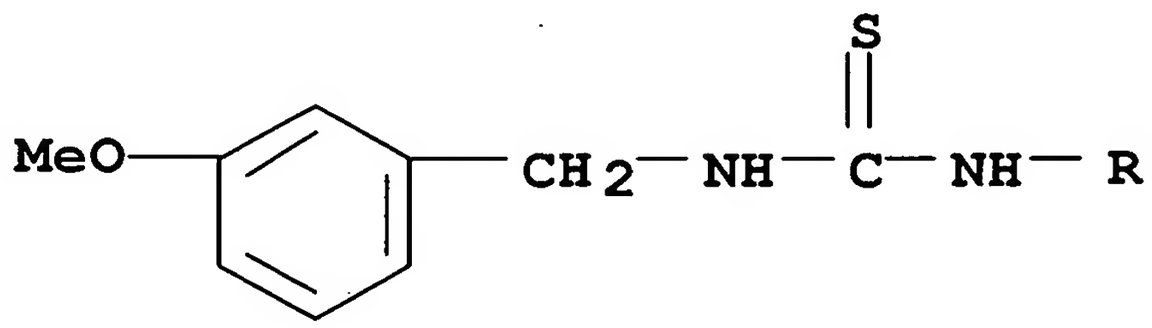
I



wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is selected from the group consisting of 1,3-di(3-methoxybenzyl) thiourea; 1-(3-methoxybenzyl)-3-ethyl-2-thiourea; 1-(3-methoxybenzyl)-3-propyl-2-thiourea; 1-(3-methoxybenzyl)-3-hexyl-2-thiourea; 1-(3-methoxybenzyl)-3-dodecyl-2-thiourea; 1-(3-methoxybenzyl)-3-(4-hydroxyphenyl)-2-thiourea; and 1-(3-methoxybenzyl)-3-(3-methoxyphenyl)-2-thiourea, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, and wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition.

15. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

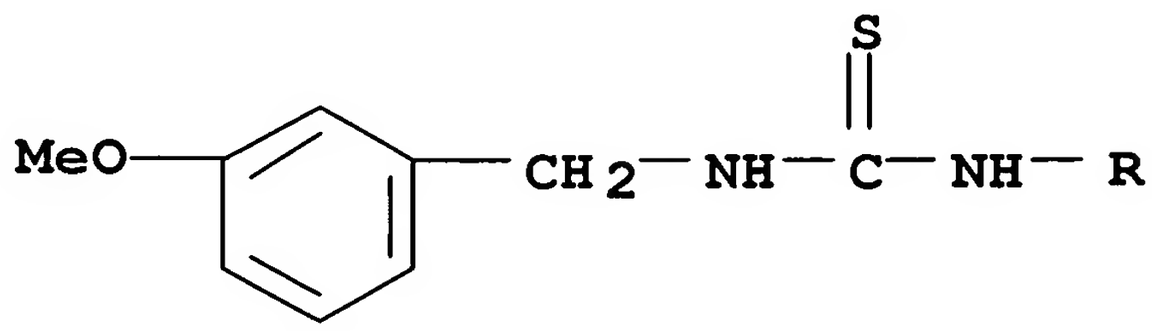
I



wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition, and wherein the composition further comprises a sunscreen compound in a concentration effective for sunscreen protection.

16. A composition comprising a base composition and at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

I



wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, wherein the compound of formula I is present in the composition in an amount effective to inhibit free radical polymerization, wherein the composition inhibits free radical degradation of skin or hair of a human or nonhuman animal after contacting the skin or hair with the composition and wherein the composition of formula I is 1,3-di(3-methoxybenzyl) thiourea.

17. A composition according to claim 15 wherein the base composition comprises an oil that contains the compound of formula I.

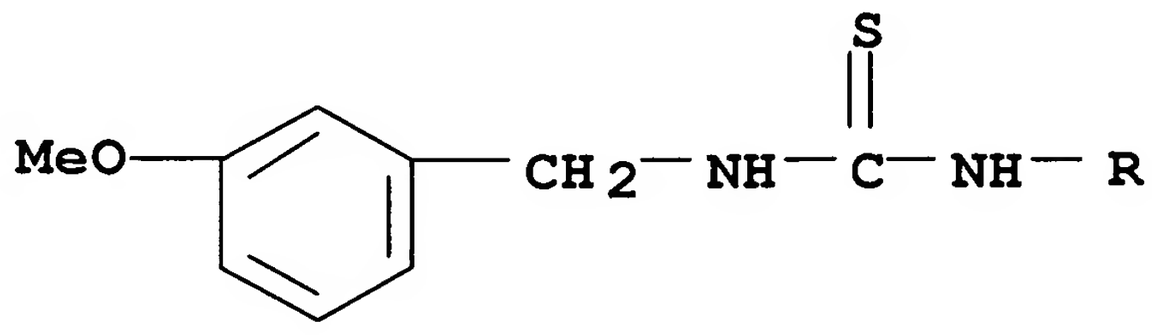
18. A composition according to claim 17 wherein the composition is an emulsion.

19. A composition according to claim 17 wherein the oil is meadowfoam seed oil.

20. A composition according to claim 14 which further comprises a sunscreen compound in a concentration effective for sunscreen protection.

21. A method for inhibiting free radical degradation of skin or hair of a human or nonhuman animal comprising contacting the skin or hair with a composition comprising at least one 1-(3-methoxybenzyl)-3-substituted thiourea compound of formula I:

(I)



in a concentration which is effective to inhibit free radical polymerization, wherein R is selected from the group consisting of C_1 - C_{20} linear or branched alkyl; C_5 - C_7 cycloalkyl; alkoxy-substituted C_5 - C_7 cycloalkyl; hydroxy-substituted C_5 - C_7 cycloalkyl; C_6 - C_7 aryl; hydroxy-substituted C_6 - C_7 aryl; and alkoxy-substituted C_6 - C_7 aryl, with the proviso that, if the composition contains an oil in which a compound of formula I is naturally occurring in an amount effective to inhibit free radical polymerization, the composition further comprises an additional amount of a compound of formula I which is effective to inhibit free radical polymerization, which additional amount is exogenous to the naturally-occurring amount.

Argument

For the reasons set forth below, Applicants respectfully submit that a *prima facie* case of obviousness of the subject matter that is described in claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application, as these claims have been amended in the amendments set forth hereinabove, over the subject matter that is described in claims 1-21 of the '052 patent, has not been established. Applicants submit that the subject matter that is described in claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application is patentably distinguished from the subject matter that is described in claims 1-21 of the '052 patent (i.e., that none of claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application defines merely an obvious variation of the subject matter that is described in claims 1-21 of the '052 patent).

First, Applicants respectfully submit that several structural, chemical and other differences exist between the subject matter that is described in claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application, as these claims have been amended hereinabove, and the subject matter that is described in claims 1-21 of the '052 patent, and that such differences are such that the subject matter described in claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Further, for the reasons set forth hereinbelow, Applicants submit that the subject matter that is described in claims 1-21 of the '052 patent would not have suggested the invention that is described in claims 1-4, 7-11, 15-17, 33-36, 40 and 41 of the application to one of ordinary skill in the art.

Independent claim 1 of the application (and dependent claims 4, 7-10, 40 and 41) contains:

(a) a limitation stating that, "wherein the compound enhances the stability of a lipid or oil to which the compound is added"; and

(b) a proviso stating, "with the proviso that R is not phenyl, octyl or octadecyl."

Moreover, dependent claims 4, 7-10, 40 and 41 of the application each contain additional limitations.

Independent claim 11 of the application (and dependent claims 15-17) contains:

(a) a limitation that the base lipid or oil described therein is supplemented "with an oxidative stability-enhancing amount" of a compound set forth therein;

(b) a limitation stating, "wherein the composition has a greater oxidative stability than an oxidative stability of the base lipid or oil prior to supplementation with the compound"; and

(c) a new proviso stating, "with the proviso that the compound is not 1,3-di(3-methoxybenzyl) thiourea."

Moreover, dependent claims 15-17 of the application each contain additional limitations.

Independent claim 33 of the application (and dependent claims 34-36):

(a) states that it is a method for "enhancing the oxidative stability of a base lipid or oil"; and

(b) contains a limitation that the base lipid or oil described therein is combined "with an oxidative stability-enhancing amount" of a compound set forth therein.

Moreover, dependent claims 34-36 of the application each contain additional limitations.

Applicants respectfully submit that none of the above-described limitations that are present in any of independent claim 1 (and claims 4, 7-10, 40 and 41, which depend upon claim 1), independent claim 11 (and claims 15-17, which depend upon claim 11) and/or independent claim 33 (and claims 34-36, which depend upon claim 33) of the application are taught or suggested by any of claims 1-21 of the '052 patent. None of these claims discusses anything about an enhancement of an oxidative stability of a lipid or oil. These claims are all directed to compositions that perform a completely different function (an inhibition of free radical degradation in skin and hair), which is clearly indicated by limitations that are present in each of these twenty-one claims.

Further, the methods that are described in claims 33-36 of the application are completely different methods than the methods that are described in claims 1-11 and 21 of the '052 patent, and the substrates employed in the two groups of methods are completely different. The former methods are performed to enhance an oxidative stability of a base lipid or oil, wherein the base lipid or oil (substrate) is combined with a a substituted thiourea compound in an oxidative stability enhancing amount. The latter methods are performed to accomplish a completely different purpose. These methods are performed to inhibit free radical degradation of skin or hair of a human or nonhuman animal, wherein the skin or hair (substrate) is contacted with a substituted thiourea compound in a concentration that is effective to inhibit free radical polymerization.

In the office action (page 3), the examiner made an inquiry as to why the present compound/composition claims were not filed (claimed) along with the method claims of the application that issued into the '052 patent. The reason is that, as is discussed hereinabove, and as is discussed in the two Declarations that have been submitted by Dr. Abbott, the rejected claims of the present application describe compounds, compositions and methods that are different from the compounds, compositions and methods that are described in the '052 patent. If the examiner compares the file for the present application with the file for the '052 patent, the examiner will see that the both the inventorship and

assignee listed for the two files are different. The different inventions were invented by different inventive entities to accomplish a completely different purpose, and were assigned to different assignees.

Applicants respectfully submit that the differences that exist between the compounds that are described in claims 1-21 of the '052 patent and the rejected claims are patentable differences.

As is discussed hereinabove, the disclosure of the '052 patent cannot be employed in support of a double patenting rejection. Thus, claims 1-21 of the '052 patent do not teach or suggest all claim limitations, as is required to establish a *prima facie* case of obviousness.

Further, because claims 1-21 of the '052 patent describe (in each of the claims themselves) a completely different utility for the compounds, compositions and methods described therein (an inhibition of free radical polymerization in skin and hair) in comparison with the utility described in each of the rejected claims of the application (an enhancement of an oxidative stability of a base lipid or oil), claims 1-21 of the '052 patent do not provide a motivation for one of ordinary skill in the art to make the compounds, compositions and methods that are described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application.

In view of the discussion above, it is clear that claims 1-21 of the '052 patent would not have suggested the invention that is described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application to one of ordinary skill in the art.

Assuming arguendo that it would have been obvious to try to prepare the compounds and compositions, and to try the methods, that are described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application in view of claims 1-21 of the '052 patent, which Applicants submit that is was not, the Federal Circuit has held that "obvious to try" is not the standard under §103. [In re O'Farrell, *supra*.]

Second, for the reasons set forth below, Applicants respectfully submit that the subject matter that is described in claims 1-21 of the '052 patent would not have suggested that the invention that is described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application would have a reasonable likelihood of success.

In his enclosed second Declaration, Dr. Abbott states that it is his opinion as an expert in the area of thiourea compounds that, for the reasons set forth therein, the subject matter that is described in claims 1-21 of the '052 patent would not have suggested that the invention that is described in any of claims 1, 4, 7-36, 40 and 41 of the application (as these claims have been amended in an accompanying amendment and response to the office action) would have a reasonable likelihood of success.

As is discussed hereinabove in detail, a significant amount of unpredictability exists in the art of disubstituted thiourea compounds, to which the compounds, compositions and methods that are described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application are directed. Further, thiourea compounds that may appear to have similar chemical structures may have very different chemical properties.

Further, Applicants submit that there is no teaching, suggestion or other indication from claims 1-21 of the '052 patent (with or without the use of the disclosure, which is prohibited) that the compounds, compositions and methods that are described in claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 of the application would have an ability to successfully enhance the oxidative stability of a base lipid or oil to which substituted thiourea compounds are added (a limitation that is present in each of the rejected claims). Claims 1-21 of the '052 patent do not discuss an enhancement of an oxidative stability of a base lipid or oil and, in fact, describe a completely different application for the compounds, compositions and methods described therein. Claims 1-21 of the '052 patent each describe an inhibition of free radical degradation of skin or hair of a human or nonhuman animal.

The examiner is referred to the discussion set forth by Applicants hereinabove under "1. Rejection of Claims 1, 2, 5, 37 and 39 under 35 U.S.C. §101" and "2. Rejection of Claims 11-14 and 18-32 under 35 U.S.C. §101", and to the first and second Declarations of Dr. Abbott, all of which are incorporated into this section of this amendment and response in their entireties by reference, and will not be repeated in full here, with the exception of a few important excerpts.

In his second Declaration, Dr. Abbott states that it is clear from a review of claims 1-21 of the '052 patent and claims 1, 4, 7-36, 40 and 41 of the application that the problems that the inventors of the invention described in the '052 patent were attempting

to solve are completely different from the problem with which the inventors of the invention described in the rejected claims of the present patent application were concerned.

Further, in his second Declaration, Dr. Abbott states that the chemical mechanisms for inhibiting free radical degradation of the skin or hair of a human or nonhuman animal and related properties are substantially different from the chemical mechanisms for enhancing an oxidative stability of a lipid or oil to which a disubstituted thiourea compound has been added.

Moreover, in the second Declaration, Dr. Abbott discusses an article entitled, "Review, The Problems of Using One-Dimensional Methods to Evaluate Multifunctional Food and Biological Antioxidants," in which the authors describe the unpredictable nature of antioxidant activity and a variety of factors that influence antioxidant activity, including the type of substrate and the temperature of the testing conditions, and show that the effectiveness of antioxidants is strongly dependent on the test system, the physical states of the lipid substrates, the conditions of oxidation, the oxidizing substrate, the localisation of antioxidants and the method employed to evaluate oxidation and the stages of oxidation.

In his second Declaration, Dr. Abbott also states that the OSI test that is described in the present application measures specifically the low molecular weight breakdown products of oxidation of lipids. In contrast, he states that the test described in the '052 patent measures the prevention of the formation of high molecular products by free radical crosslinking of protein in skin and hair.

Dr. Abbott further states in his second Declaration that any one of the compounds or compositions that are described in the rejected claims of the application may have additional properties or applications as yet undiscovered. For example, he states that it is well established that natural products having cellular reproductive inhibition in the brine shrimp assay as described in Abbott et al. (Industrial Crops and Products 16, 46-53 (2002)) may also inhibit cancer cells and have therapeutic value. He states that some of the compounds that have been determined to be most effective in the present application, such as 1,3-di(3-methoxybenzyl) thiourea, were determined to be the least effective in cellular inhibition in the above-cited Abbott et al. publication. He states that the same

logic should be applied to the free radical inhibition in hair and skin compared with oxidative stability enhancement.

Dr. Abbott further states in his second Declaration that the subject matter that is described in the rejected claims of the present application is different in both the mechanism of action, and the substrate on which it acts, in comparison with the subject matter that is claimed in the '052 patent. He states that, preventing damage to hair and skin by free radicals is accomplished by reacting with high energy free radicals, specifically reactive oxygen species, as is described in the Background of the Invention section of the '052 patent. He further states that enhancing antioxidative effects in oils with the addition of the compounds and compositions that are described in the rejected claims of the application, in contrast, is accomplished by decomposing hydroperoxy derivatives of the oils, before the oils proceed to the next step to decomposition to aldehydes and acids.

In conclusion, Applicants submit that independent claims 1, 11 and 33 of the application, and each of the claims that depend upon these independent claims, are nonobvious under 35 U.S.C. §103. [See In re Fine, *supra*.]

In view of the amendments and discussion presented by Applicants hereinabove, the examiner is respectfully requested to withdraw the rejection of claims 1, 4, 7-11, 15-17, 33-36, 40 and 41 under the judicially created doctrine of obviousness type double patenting over claims 1-21 of the '052 patent.

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If, after considering this amendment and response, the Examiner believes that any issues still remain in the prosecution of the application, the Examiner is respectfully requested to telephone Applicants' attorney at a telephone number set forth hereinbelow.

Applicants filed a general authorization for a petition for an extension of time under 37 C.F.R. §1.136(a)(3) for the application with the U.S. Patent and Trademark Office ("Patent Office") on August 1, 2003. In accordance with this petition, Applicants are requesting that the time for replying to the present office action be extended one month (i.e. from August 18, 2005 to September 18, 2005). The $120.00 fee to cover the

cost of this one-month extension of time in accordance with 37 C.F.R. §1.17(a), and any other fees that may be required for the proper filing of this amendment and response and accompanying documents with the Patent Office, are hereby authorized to be deducted by the Patent Office from Deposit Account No. 122144.

Respectfully submitted,

LORD, BISSELL & BROOK LLP

By: Roberta L. Hastreiter

Roberta L. Hastreiter
Registration No. 32,990

September 16, 2005

LORD, BISSELL & BROOK LLP
115 South La Salle Street
Chicago, Illinois 60603
Telephone: (770) 410-1244; (312) 443-0700
Facsimile: (312) 443-0336